

# 10 Evaluating Clinical Trials



Conducting studies on people is time-consuming and expensive. Researchers need funding. The U.S. National Institutes of Health (NIH) is one organization that provides money for such studies. What does NIH look for when researchers request money to study people scientifically?



Which proposals have an experimental design worth funding?

## *The NIH Committee*

Listed on the following pages are proposals for four studies requesting money to conduct clinical trials. Most of the studies are based on actual research projects. As a member of the NIH review committee, your job is to evaluate the experimental design of each proposed study. Based on your review, make a recommendation as to whether NIH should fund each study.

## MATERIALS



*For each student*

- 1 Student Sheet 10.1, "Reviewer Comments"
- 1 Student Sheet 10.2, "Discussion Web: Evaluating Clinical Trials"

## PROCEDURE

1. With your group, brainstorm all of the factors that are important in designing a scientific experiment involving people. Work together to agree on a complete list.
  - Listen to and consider the explanations and ideas of other members of your group.
  - If you disagree about a factor with others in your group, explain to the rest of the group why you disagree.
2. Read Study 1, "Clinical Trial of 'Summer Fever' Vaccine." (The studies begin below.)
3. Use your list of experimental design factors from Step 1 and Student Sheet 10.1, "Reviewer Comments," to evaluate the study. Record the name of the study, the factors of its experimental design, and any other comments you have.
4. Based on your comments, decide whether you would recommend funding for this study.
5. Repeat Steps 2–4 for the remaining studies.

### Study 1: Clinical Trial of "Summer Fever" Vaccine

We are working to prevent "summer fever," a contagious disease that kills or paralyzes many children each summer. The disease attacks the motor neurons of the body, which control the muscles, causing paralysis. Sometimes the disease attacks the nerves in the base of the brain and then swallowing and breathing are affected. This disease is spreading quickly across the



*This child's legs are paralyzed as a result of a disease similar to "summer fever."*

United States. We have developed a vaccine that we believe will prevent children from catching this disease. We would like to conduct a clinical trial to find out if our vaccine is effective in children. Our plan is to give the vaccine to 12,000 children in the state's capital city. We will count how many of these children catch summer fever. We are sure that all of these children will be completely protected as a result of taking this vaccine.

To prove that the vaccine is safe for humans, my assistant, my 14-year-old child, and I have all taken it. We have not suffered any bad effects from the vaccine.

### Study 2: Clinical Trial of Burn Cream

We have developed a new, medicated cream that helps heal burns on animals. Faster healing reduces pain and reduces the chance that the burns will become infected. We would like to test this cream on humans to see if it helps heal their burns faster. We plan to conduct clinical trials on 200 people ages 20–40. Half of the people will be men and half will be women. Each person must have third-degree burns that are no larger than 3 centimeters by 3 centimeters. They must also be healthy except for their burns.

Fifty of the men and fifty of the women will be treated with our new medicated cream. The other half will receive a placebo cream that does not contain the medication. We will not let either group know which cream they are receiving. Each person will apply 2 grams of cream to the burn every morning for 20 days.

Three studies done by the local veterinary school have shown that the medicated cream is effective in healing burns on rabbits, cats, and dogs. Each study involved 100 animals. Half of the animals received medicated cream and half received cream without medication. The burns on animals treated with medicated cream healed faster.

### Study 3: Clinical Trial of Weight Loss Method

More than half of the adults in the United States are overweight. Many of them try risky fad diets to lose weight. One way to help people lose weight is to find effective ways in which they can reduce the number of calories they eat. For this reason, we would like to conduct a clinical trial of one method of reducing calorie intake. We would like to find out whether drinking water and eating an appetizer before a meal will help people reduce the number of calories they eat.

We will begin with 24 volunteers who will be told about all aspects of the trial. We will select volunteers who are men between the ages of 35–55 and who are at least 20% overweight. In our control, each volunteer will eat a chicken-rice appetizer that contains exactly 200 calories. We will then count how many calories the volunteer eats for lunch after eating this appetizer. To measure the effect of drinking water with the appetizer, the same volunteer will eat the same appetizer on a different day, but this time with a 12-ounce glass of water. We will again count the number of calories the volunteer eats for lunch afterward.

Each volunteer will repeat the control and the experiment three times. We will then average the results to determine any change in the number of calories eaten in each part of the trial.



### Study 4: Clinical Trial of Relaxin

We have developed a new drug called Relaxin. We believe Relaxin can be used to calm and relax people as well as prevent nausea. For these reasons, we think this drug would be useful to pregnant women. We would like to conduct a clinical trial to find out if this drug is effective for pregnant women. We will provide Relaxin to some doctors. These doctors will be asked to prescribe Relaxin to pregnant women who ask for a drug to prevent nausea. Of course, we will tell the women that they are getting Relaxin, because people testing new drugs should give their permission. We will then record the effects on these women by asking them if they feel calmer and less nauseated.

Relaxin has been tested for its effectiveness and safety. Our scientists conducted an experiment on mice. Half of these mice were given Relaxin, while the other half were given a placebo. We observed and recorded how much the mice moved. The mice that were given Relaxin moved less than the mice that were given the placebo. This showed that the drug is effective. None of the mice

had any side effects from this drug. To further test the safety of Relaxin, we gave large doses to some mice. None of these mice showed any permanent side effects from the large doses.

## ANALYSIS



1. Which study—1 through 4—had the best experimental design? Explain.
2. Discuss your funding recommendations with your group. Do you agree on which studies, if any, should be funded? What other concerns do you have?



3. You find out that NIH has only enough money to fund one study and plans to fund the best one. Explain which study you would fund. Support your answer with evidence and identify the trade-offs of your decision.

**Hint:** To write a complete answer, first state your opinion. Provide two or more pieces of evidence that support your opinion. Then consider all sides of the issue and identify the trade-offs of your decision.



4. Choose one of the studies. Review your comments about its experimental design and think about how the study could be improved. Rewrite the study to include your recommendations for improving the quality of the experiment.

5. **Reflection:** Based on what you have learned in this unit, how do you solve problems? How do scientists solve problems? Compare your methods to scientists' methods and describe the similarities and differences between them.

## EXTENSION

Bring in news articles that describe scientific studies involving people. Analyze the studies according to the procedures you used in this activity. What issues do scientists face when studying people scientifically?